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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,436	06/30/2003	Istvan Toth	36677.11	9341

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HAYNES AND BOONE, LLP
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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	**PAPER NUMBER**
1623	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,436	TOTH ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13 and 16-38* is/are pending in the application.

4a) Of the above claim(s) *18 and 20-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-13, 16-17, 19 and 24-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 4/4/2007 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 2 and 14-15 have been canceled.

2. New Claim 38 has been added.

3. Claims 1, 5-7, 9, 12, 19, 28 and 35-37 have been amended.

4. Remarks drawn to rejections under 35 USC 103.

Claims 1, 3-13 and 16-38 are pending in the case. Claims 18 and 20-23 have been withdrawn. Claims 1, 3-13, 16-17, 19 and 24-38 are under consideration.

The following rejection necessitated by amendment is made of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-13, 16-17, 19 and 24-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekany et al (Peptides, 1996, 331-32) of record in view of Neubert (Pharmaceutical Research, 1989, 6(9), 743-749; document C10 in IDS of 218/2005) newly cited.

Dekany et al disclose a lipidic moiety containing sugar compound (page 332, structural formula 2). In this structure the lipidic moiety (shown to the right in the structure; L in instant claim 1) is attached to a monosaccharide (S in the instant claims) via a linker (NH group). The sugar bearing the lipidic moiety is attached to another sugar. A sugar molecule is a therapeutically useful molecule. Structure 2 of Dekany meets the limitations of instant formula I for W being absent.

The linker, NH in structure 2 of Dekany, is attached to the sugar unit through the glycosidic position. The term glycosidic position is not defined by the claim. Hence any position on the sugar moiety is interpreted as a glycosidic position. Since the attachment of the lipidic moiety to the sugar is via a nitrogen atom and a CONH group is present, the attachment to the monosaccharide is via an N-glycoside and an amide bond. The linker, NH, is attached to the lipidic moiety $(C(O)CH\text{-}(NHR^2)\text{-}(CH)_2\text{-}CH_3$ group in structure 2 of Dekany, via an amide bond.

In structure 2 of Dekany lipidic moiety L is composed of the group – $C(O)CH-(NHR^2)-(CH)_2-CH_3$. This structure is same as structure IIa for R1= hydrogen and R2 = linear alkyl chain having 16 carbons and both R1 and R2 are not hydrogens at the same time. The lipid moiety in structure 2 of Dekany has an NHR^2 group attached to it, which can be charged. In structure 2 of Dekany the sugar unit in the middle (mono saccharide) is attached to a lipidic moiety containing one lipoaminoacid meeting the structural formula IIa in instant claim 12. Dekany suggests the coupling of the conjugate of his invention to peptides and drugs (page 332, paragraph below structure 2). The physico chemical properties of the conjugates were modified by varying the nature and the number of sugars, the number of lipoaminoacids or the length of their alkyl chain. According to Dekany complexation of the conjugate (structure 2, page 332) to drugs and peptides will enhance the water solubility in drug delivery and increase the immunogenicity of synthetic peptides. However, Dekany does not teach compounds wherein the sugar moiety is substituted with alkyl or heteroalkyl spacers carrying functional groups that can carry a charge.

According to Neubert the lipophilicity of drugs can be increased by ion pair formation with lipophilic counterions (page 743, first two lines of the first full paragraph on the right column and conclusion at page 746). Neubert also teaches that the key is the use of specific lipophilic counter ions with a convenient physiological compatibility (page 746, last two lines). From this teaching of Neubert one of ordinary skill in the art will recognize that inorder to increase the bioavailability of drugs ionic complexes that have ion pairs are important and the more ion pairs that form the more the solubility. Since Dekany teaches compounds that have a sugar and lipophilic moiety, both of which are biocompatible and have alkyl groups that can carry a charge (amino groups), it would be logical to have more of such alkyl chains with

functional groups that are capable of carrying a charge. This would result in the formation of several ion pairs, which in turn would increase the bioavailability and transport of drugs. A logical step would be to have these additional charge bearing groups on the carbohydrate moiety of the compound of Dekany.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make complexes of formula I and their compositions as instantly claimed with a reasonable expectation of success since the prior art teaches the preparation of such complexes using the components as instantly claimed. Introduction of alkoxy groups containing other functional groups is well known to one of ordinary skill in the art.

One of ordinary skill in the art would be motivated to make such compounds and compositions since such a complex with drugs and peptides increases their water solubility and hence would be useful in drug delivery as taught by Dekany. It is well within the purview of one of ordinary skill in the art to extend this to mono and oligosaccharides and several drugs for the purpose of enhanced drug delivery.

Response to Applicants Remarks

Applicants have amended the instant claims to include the component W in formula (I) and argue that Dekany does not teach the complex comprising O-alkyl groups and related spacer groups attached to the mono or oligosaccharide. The rejection above, necessitated by amendment is advanced.

Conclusion

Claims 1, 3-13, 16-17, 19 and 24-38 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

6/18/07

Shaojia Jiang
Supervisory Patent Examiner
Art Unit 1623